

**REMARKS**

This is a response to the Office Action of August 22, 2006.

**I. SUMMARY OF OFFICE ACTION**

Claim 34 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1, 19-21, 23, 26, 29, 30, 32, 35, 36 and 38 were rejected under 35 U.S.C. §102(b) as being anticipated by Kniewasser (WO99/24101).

Importantly, the Examiner indicated that Claims 18, 22, 24, 25, 27, 28, 33 and 37 were merely objected to as being dependent upon a rejected base claim, but indicated that such claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**II. APPLICANT'S RESPONSE**

**A. Claim 1**

In the Office Action, Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Kniewasser. In response, the Applicant has amended Claim 1 to further recite that the axis of the gas inlet channel is laterally offset from an axis of the breathing channel...such that a part of the gas introduced by the gas inlet channel bypasses the breathing channel to flow down the exhaust channel to permit the pressure in the breathing channel during inhalation to be greater than the pressure in the breathing channel during exhalation. The basis for the amendment may be found at Col. 7, Line 33-Col.8, Line 3 and Col. 10, Ins. 16-20 of the instant specification.

Applicant respectfully submits that Kniewasser does not disclose an axis of the gas inlet channel laterally offset from an axis of the breathing channel such that a part of the gas introduced by the gas inlet channel bypasses the breathing channel to flow down the exhaust channel to permit the pressure in the breathing channel during inhalation to be greater than the pressure in the breathing channel during exhalation. Referring now to the representative figure of Kniewasser, part 50 is believed to be the gas inlet channel because the abstract

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states that airflow (A) is introduced into the hollow body 10. Opening 20 is believed to be the exhaust channel because the abstract states that the opening 20 allows...for the discharge of the exhaled air (B). Parts identified as reference numeral 35 is believed to be the breathing channel because the abstract states that the fitting 30 provides for connecting the hollow body 10 to a nasal and/or mouth piece. As can be seen from the representative figure, it is believed that all of the gas introduced by the gas inlet channel does not bypass the breathing channel. Rather, all of the gas introduced by the gas inlet enters the hollow body 10 and subsequently into the breathing channel 35. Moreover, the device of Kneiwasser does not provide a greater pressure in the breathing channel during inhalation compared to exhalation. Accordingly, for the foregoing reasons, Applicant respectfully submits that Kniewasser does not disclose an axis of the gas inlet channel laterally offset from an axis of the breathing channel...such that a part of the gas introduced by the gas inlet channel bypasses the breathing channel to flow down the exhaust channel to permit the pressure in the breathing channel during inhalation to be greater than the pressure in the breathing channel during exhalation.

Moreover, there is no motivation to modify the device of Kniewasser such that the axis of the gas inlet channel is laterally offset from the axis of the breathing channel...such that a part of the gas introduced by the gas inlet channel bypasses the breathing channel to flow down the exhaust channel to permit the pressure in the breathing channel during inhalation to be greater than the pressure in the breathing channel during exhalation. The reason is that to do so would change the principle of operating the device of Kniewasser. (see MPEP § 2143.01 (V)). The device of Kniewasser relates to a constant continuous positive air pressure device. As understood, the positive pressure in the breathing channel is constant throughout the patient's inhalation and exhalation cycle based on a contention that the air (A) flows at a constant rate into the hollow body 10.

In contrast, in the invention recited in Claim 1, the positive pressure maintained in the breathing channel may fluctuate such that the pressure in the breathing channel (1) increases in the breathing channel during inhalation and (2) decreases during exhalation. Accordingly, if the device of Kniewasser was modified such that the axis of the gas inlet channel is laterally offset from the axis of the breathing channel to fluctuate the pressure in the

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breathing channel based on whether the patient is inhaling or exhaling, then such modification would alter the principle of operation of the device of Kniewasser from a constant positive pressure in the breathing channel to a fluctuating positive pressure in the breathing channel. Accordingly, there is no motivation to modify the device of Kniewasser, as discussed above, based on a contention that to do so would alter the principle of operation of the device of Kniewasser. Hence, Claim 1 is believed to be in condition for allowance.

#### **B. Claim Rejections—35 U.S.C. §112**

In the Office Action, Claim 34 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In response, Applicant has amended Claim 34 to recite that the cross sectional area of the gas inlet channel is approximately less than about one-fourth the cross sectional area of at least one of the breathing and exhaust channels. Applicant respectfully submits that the basis for such amendment is found in the specification at Col. 5, Lines 33-34. Accordingly, such amendment to Claim 34 overcomes the rejection of Claim 34 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

#### **C. Claims 18-30 and 32-34**

In the Office Action, Claim 22 was objected to as being dependent upon a rejected base claim. Importantly, the examiner indicated that Claim 22 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. By this amendment, Applicant has amended Claim 22 to include the limitations of its base Claim 1. Hence, Claim 22 is believed to be in condition for allowance.

The dependent claims of Claim 22 is believed to be in condition for allowance for containing additional patentable subject matter. By way of example and not limitation, Claim 32 recites similar subject matter as the subject matter amended into Claim 1 above. For the same reasons discussed above in relation to Claim 1 above, Applicant' respectfully submits that Claim 32 is believed to be in condition for allowance. Hence, the dependent claims of Claim 22, namely, Claims 18-21, 23-30 and 32-34 are believed to be in condition

for allowance for containing additional patentable subject matter and for also being dependent upon an allowable base Claim 22.

**D. Claim 35**

In the Office Action, Claim 35 was rejected under 35 U.S.C. §102(b) as being anticipated by Kniewasser. Applicant respectfully submits that Kniewasser does not anticipate the invention recited in Claim 35 based on a contention that Kniewasser does not disclose an axis of the gas inlet channel being directed towards an inner edge of the junction between the breathing and exhaust channels.

As discussed above in relation to Claim 1, part 50 in Kniewasser is believed to be the gas inlet channel. Opening 20 is believed to be the exhaust channel. Also, part 35 is believed to be the breathing channel. As understood, the axis of the gas inlet channel is not directed towards an inner edge of the junction between the breathing and exhaust channels. It is believed that the inner edge of the junction between the breathing and exhaust channels may be considered to be edge "C" identified in Exhibit A (marked up representative figure of Kniewasser) submitted concurrently herewith. As understood, the axis "D" of the gas inlet channel is directed away from the inner edge "C" of the junction between the breathing and exhaust channels in Kniewasser. Hence, the Kniewasser reference does not disclose all of the limitations of the invention recited in Claim 35.

Additionally, there is no motivation to modify the device of Kniewasser such that the axis of the gas inlet channel is directed towards the inner edge of the junction between the breathing and exhaust channels based on a contention that to do so would change the principle of operation of the device of Kniewasser. As discussed above, the device of Kniewasser provides a positive pressure maintained at a constant level in the breathing channel. In contrast, the invention recited in Claim 35 may operate to provide fluctuating pressure in the breathing channel based on whether the patient is inhaling or exhaling. Accordingly, modifying the device of Kniewasser such that the axis of the gas inlet channel is directed towards the inner edge of the junction between the breathing and exhaust channels would change the principle of operating the device of Kniewasser from maintaining a constant positive pressure in the breathing channel to fluctuating the positive pressure in the breathing channel. Accordingly, there is no motivation to modify the device of Kniewasser

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such that the axis of the gas inlet channel is directed towards the inner edge of the junction between the breathing and the exhaust channels.

For the foregoing reasons, Applicant respectfully submits that Claim 35 is believed to be in condition for allowance.

#### **E. Claims 36-38**

In the Office Action, Claim 37 was objected to as being dependent upon a rejected base claim. Importantly, the examiner indicated that Claim 37 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. By this amendment, Applicant has amended Claim 37 to include all of the limitations of its base Claim 35. Hence, Claim 37 is believed to be in condition for allowance.

The dependent claims of Claim 37 are believed to be in condition for allowance for containing additional patentable subject matter. By way of example and not limitation, Claim 38 discusses the “increased pressure during inhalation compared to exhalation” subject matter discussed above in relation to Claim 1. Accordingly, Claim 38 is also believed to be in condition for allowance for containing additional subject matter.

Moreover, the dependent claims of Claim 37, namely, Claims 36 and 38 are believed to be in condition for allowance for containing additional patentable subject matter and for also being dependent upon an allowable base Claim 37.

#### **III. CONCLUSION**

For the foregoing reasons, Applicant respectfully submits that Claims 1, 18-30, and 32-38 are believed to be in condition for allowance. An early Notice of Allowance is therefore respectfully requested. Should the Examiner have any suggestions for expediting allowance of the above-identified application, the Examiner is invited to contact Applicant’s representative at the telephone number listed below.

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Should any additional fee be required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

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INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE  
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(54) Title: SPONTANEOUS BREATHING DEVICE WITH CONTINUOUS POSITIVE AIR PRESSURE (CPAP DEVICE)

(54) Bezeichnung: VORRICHTUNG ZUR ERZEUGUNG EINES KONTINUIERLICHEN POSITIVEN ATEMWEGDRUCKS (CPAP-VORRICHTUNG)

#### (57) Abstract

The invention relates to a continuous positive air pressure device (CPAP device) for spontaneous breathing, especially a nasal CPAP device (nCPAP device). The inventive device includes a hollow body (10) in which it is possible to generate a positive pressure. A first opening (20) provided in a side wall of the hollow body (10) allows for the introduction of an air flow (A) in the hollow body (10) and for the discharge of the exhaled air (B). A fitting (30) attached to the hollow body (10) is provided for connecting the hollow body (10) to a nasal and/or mouth piece (100) and a spacer (40) also attached to the hollow body (10) comprises a flow nozzle (50) for directing the air flow (A) towards the opening (20).

#### (57) Zusammenfassung

Die vorliegende Erfindung schafft eine Vorrichtung zur Erzeugung eines kontinuierlichen positiven Atemwegdrucks (CPAP-Vorrichtung), insbesondere nasale CPAP-Vorrichtung (nCPAP-Vorrichtung), mit einem Hohlkörper (10), in dem ein Überdruck aufbaubar ist; einer in einer Seitenwand des Hohlkörpers (10) vorgesehenen ersten Öffnung (20) zum Zuführen einer in den Hohlkörper (10) gerichteten Luftströmung (A) und zum Abführen der ausgeatmeten Luftströmung (B); einem am Hohlkörper (10) anbringbaren Anschlußstück (30) zur Verbindung des Hohlkörpers (10) mit einem Nasen- und/oder Mundansatzstück (100) und einem am Hohlkörper (10) anbringbaren Abstandshalter (40), an dem eine Strömungsdüse (50) zum Richten der Luftströmung (A) auf die Öffnung (20) anbringbar ist.

